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Genetic privacy and non-discrimination

Report of the Secretary-General

Summary

The present report includes information and comments received from Member States and entities of the United Nations system on Economic and Social Council resolution 2004/9 entitled "Genetic privacy and non-discrimination". The report highlights the potentials and dangers of new developments in the genetic field and reviews initiatives taken to provide a framework for ensuring respect for genetic privacy and non-discrimination, including the United Nations Educational, Scientific and Cultural Organization (UNESCO) Universal Declaration on Bioethics and Human Rights, a major development at the international level since the Council considered the matter in 2004. The report concludes with recommendations on how the Council could proceed on this matter.

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I. Introduction

1. The Economic and Social Council considered the issue of genetic privacy and non-discrimination at its 2001 and 2004 sessions.[1] In 2004, the Council adopted resolution 2004/9, in which it urged States to ensure that no one is subjected to discrimination based on genetic information. The Council further encouraged the adoption of measures in various fields to protect citizens from the use and misuse of genetic information leading to discrimination and promoted international efforts to support activities in this field. The Council decided to continue considering the various implications of the question of genetic privacy and non-discrimination for ethical, legal, medical, employment, insurance-related and other aspects of social life, consistent with public international law and international human rights law, and requested the Secretary-General to bring the resolution to the attention of all Governments, relevant international organizations and functional commissions, to collect the comments received pursuant to it and other relevant information and to submit a report to the Council at its 2007 substantive session. The present report contains responses received by the Secretariat to a note verbale sent on the matter.

II. Information and comments received from Member States

Germany

2. In Germany, the general legal provisions governing the medical profession, combined with the provisions on data protection contained in Federal and Laender legislation, provide a framework for the protection of genetic data. The Coalition Treaty, which is the Government's programme for the current legislative period, envisages regulating human genetic testing by statute. A piece of legislation is intended to stipulate the areas where, in view of the diagnostic possibilities of human genetics, a special standard of protection is required to safeguard the privacy rights of citizens. This law would cover genetic testing for medical purposes, including prenatal genetic testing, the issue of private insurance, the workplace and the handling and protection of genetic samples and data.

Iraq

[Original: Arabic]

3. The competent Iraqi parties have examined the Secretariat communication regarding Economic and Social Council resolution 2004/9, entitled "Genetic privacy and non-discrimination", and would like to point out that, in view of the fact that the genetic fingerprint laboratory at the Institute of Forensic Medicine has not yet been fully equipped and there are no such laboratories elsewhere in Iraq at the present time, there are no measures being applied in Iraq in the area of genetic privacy and non-discrimination, as regards forensic genetic analyses at the Iraqi Ministry of Health. In this connection, the Iraqi Ministry of Health requests the United Nations Secretariat to provide it with detailed information on the paragraphs of the resolution, in particular the one that urges States to protect the privacy of those subject to genetic testing and to examine the experiences of the countries of the region in this regard.

[1] See Council resolution 2001/39, and decision 2003/232; E/2003/91 and Add.1; and E/2004/56.

Poland

4. Council resolution 2004/9 is an important and timely document to promote respect for human rights in the field of genetic privacy. The resolution addresses, inter alia, a number of issues contained in the international declarations adopted by the United Nations Educational, Scientific and Cultural Organization, namely the Universal Declaration on the Human Genome and Human Rights and the International Declaration on Human Genetic Data, which are both mentioned in the resolution, as well as the Universal Declaration on Bioethics and Human Rights adopted in 2005, one year after the adoption of Council resolution 2004/9. That important Declaration, which further asserts the link between bioethics and human rights, addresses in its articles 6 and 7 the issue of prior, free, informed and express consent that is mentioned in operative paragraph 4 of the resolution. The Declaration stresses that the possibility for the person concerned to withdraw his or her consent "at any time and for any reason without any disadvantage or prejudice" should be secured in the domains of both scientific research and medical practice (article 6, points 1 and 2).

Slovenia

5. In the field of biomedicine and particularly genetics, the protection of human rights is regulated by the Act Ratifying the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, the Convention on Human Rights and Biomedicine, the Additional Protocol to this Convention on the Prohibition of Cloning Human Beings (*Official Gazette of the Republic of Slovenia*, No. 70/98; International Treaties, No. 17/98) and the Decree ratifying the Additional Protocol to the Convention on Human Rights and Biomedicine, on Biomedical Research (*Official Gazette of the Republic of Slovenia*, No. 108/05; International Treaties, No. 20/05), in addition to other health legislation. The protocol to the convention regulating human genetics may be open for signature as early as 2007. After elaborating this protocol, Slovenia will launch the procedure for its signing and ratification.

6. The Ministry of Health will nevertheless have to continue its project of drafting a national law on human genetics in accordance with the recommendations and the proposal of the National Medical Ethics Committee.

7. The National Medical Ethics Committee, which has operated effectively on the basis of the applicable Slovenian health legislation, has submitted the following data and proposals for the implementation of Council resolution 2004/9 within the activities of the National Medical Ethics Committee relating to the protection of genetic data:

(a) A few years ago, the Committee participated in the drafting of a law on gene technology. In the parliamentary procedure, chapter 4 of the draft legislation, related to human genetics, was excluded since this area should be subject to regulation by a separate law. Work on such a law has not started yet;

(b) Through a representative of the Republic of Slovenia to the Steering Committee on Bioethics within the Council of Europe, the Committee participated in the formulation of the Oviedo Convention focusing on the protection of human genome in chapter IV. The Committee has not identified any violations of the

provisions of chapter IV (articles 11-14) in Slovenia. Nor have activities contrary to the provisions of Council resolution 2001/39 been identified;

(c) As regards ethics, the Committee reviews research studies involving intervention on human subjects in the Republic of Slovenia and research studies may not begin without approval. In the past few years, the Committee has reviewed a number of genetic research studies ranging from pharmacogenomics to population genetics. Research studies on the genetic basis of certain diseases or predisposition to diseases are particularly delicate. In this regard, the Committee complies with the provisions of the Additional protocol to the Oviedo Convention, which is on biomedical research, and the additional instrument on human genetics to the Oviedo Convention now being drafted. Clinicians and researchers are highly aware of the need to protect genetic data privacy and protect against abuse. The Committee has not yet had to reject any research studies or take any other security measures;

(d) To date, the Committee has not identified any attempt to make unjustified use of genetic testing or to discriminate on the basis of genetic data, either on the part of employers, in the insurance business or in other fields.

8. In accordance with international recommendations, a number of activities are being carried out to protect human rights in the field of human genetics through the Division of Medical Genetics (within the Department of Obstetrics and Gynecology, University Medical Centre Ljubljana), the Faculty of Medicine at the University of Ljubljana (subjects include genetics and human rights) and the Slovenian Medical Association. Within this association, the Human Genetics Association has prepared several expert reports on privacy and disclosure, genetic testing in children, presymptomatic diagnosis, storage of genetic material, etc. These expert activities are leading to regulation of and respect for human rights in genetics. They also make doctors and researchers aware of these issues. The Committee has not identified any violations in the field of genetic privacy or potential discrimination in genetic testing and the processing, use and storage of human genetic data.

Spain

[Original: Spanish]

9. In Spain, the protection of persons with regard to processing of their personal data, including those obtained from genetic testing, is governed by Organic Act 15/1999 of 13 December 1999 on the Protection of Personal Data. As stated in article 7.3 of this Organic Act, "Personal data referring to racial origin, health and sexuality may be collected, processed and disclosed only when so provided for by legislation, on grounds of general interest or if the person concerned gives his or her express consent".

10. Since recommendation No. R (97) 5 of the Committee of Ministers of the Council of Europe specifies that genetic data are data concerning health, and in accordance with the provisions of the above-mentioned article 7.3 of the Organic Act, data obtained from genetic testing may be processed only with the consent of the person concerned. The Spanish legal provisions thus comply with Council resolution 2004/9.

11. The recommendations made in the above-mentioned Council resolution are also reflected in the draft legislation on biomedical research, which, pursuant to a

proposal by the Spanish Government, has already been submitted to parliament with a view to its speedy approval.

12. It should also be noted that, in the context of the United Nations, the fundamental right to protection of personal data was expressly recognized in General Assembly resolution 45/95, adopted on 14 December 1990, concerning guidelines for the regulation of computerized personal data files (known as the United Nations data protection guidelines).

13. In this respect, since the resolution of the Economic and Social Council refers specifically to "genetic privacy", account should be taken in its implementation of all the regulatory background and the work done previously within the United Nations in this context, and specifically of the above-mentioned General Assembly resolution 45/95, which embodies precisely the principles that should govern the fundamental right to data protection.

United States of America

14. The key principles of the Government of the United States on genetic privacy and discrimination with regard to health insurance are the following:

(a) Insurers should not be able to deny enrolment for health insurance based solely on a healthy individual's genetic predisposition for a future disease;

(b) Insurers should not be able to adjust health insurance premiums based solely on the genetic predisposition of a healthy individual (or group) for a future disease; and

(c) Insurers should not request or require a genetic test as a condition for enrolment for health insurance.

Genetic discrimination in insurance

15. In the United States, the health-information privacy rule (promulgated pursuant to the Health Insurance Portability and Accountability Act (HIPAA) of 1996) protects certain individually-identifiable health information referred to as protected health information that is in the possession of health-care plans (including health insurance issuers), health-care clearinghouses, and certain health-care providers that transmit health information in connection with certain electronic transactions. The information protected in this manner includes genetic information.

16. Title I of HIPAA prohibits discrimination in enrolment in group health plans based on health status, including discrimination based solely on genetic information. HIPAA Title I also prohibits increasing the premiums or contribution rates of an individual in a group health plan (more than those charged similarly situated individuals in the plan) based on the individual's genetic information (or other health status). HIPAA Title I also prohibits group health plans and group health insurance issuers from using genetic information — in the absence of a diagnosis of a condition related to that genetic information — as the basis for a pre-existing condition exclusion. Without such a provision, a health insurer could potentially identify an individual as having a pre-existing condition based on his genetic information and then refuse to pay for treatment for the individual for that condition for a certain period of time after the date the individual enrols in the plan.

Advances in genetic medicine

17. In April 2003, the Human Genome Project published a complete DNA sequence of the human genome, the three-billion-letter genetic instruction book for a human being. This ambitious project aimed to improve human health. With the sequence of the human genome now in hand, scientists are moving rapidly to understand how all of the genes function and to develop new clinical tools, diagnostic tests and therapeutics. Genetic information can be enormously valuable to patients and providers, as it can detect potential health susceptibilities and suggest appropriate prevention strategies or interventions. As we learn more from the Human Genome Project, such clinical applications will increasingly influence the prevention and treatment options available for many common diseases.

18. Currently, approximately 680 genetic tests are clinically available and 350 more are available through research studies. The number of tests is increasing rapidly. In some cases, these tests offer patients the opportunity to learn about their individual disease-risk profile. In time, we will have a host of new preventive interventions to help people decrease their disease risks. The primary consideration should be how genetic test information will affect our health and how we, working with our doctors and other health-care providers, will be able to use this information to make good health-care decisions. But we must also be concerned that information about a patient's risk for future disease will not be used by health insurers as the sole basis to deny them insurance coverage.

Barriers to effective care

19. The National Institutes of Health (NIH) within the United States Department of Health and Human Services (HHS) have sometimes found recruitment of human research participants difficult because potential participants are concerned that their genetic information could be provided to health insurers or employers who would use the information to discriminate against them. For example, individuals in a preliminary HHS/NIH colon cancer study were provided education and counselling before being offered the genetic test. Asked what factors might lead them to take the test, the overwhelming majority stated that they wished to learn about health risks facing their children and to gain information to help them plan their own cancer screening.

20. When asked what factors might lead them not to take the test, 39 per cent of respondents said that their primary concern was losing insurance. In a similar study involving genetic testing for increased risk of breast and ovarian cancer, one third of the individuals who chose not to participate did so because of their concern about genetic discrimination. As the applications of genetics move out of the research laboratory and into broad clinical practice, this problem will intensify.

21. Thus, the fear of discrimination threatens the ability of society to use new genetic technologies to improve human health as well as the ability to conduct the research we need to understand, treat, and prevent genetic-based diseases. The challenge is to nurture scientific exploration, encourage the translation of these new discoveries into life-saving tools and to put in place public policies that prevent the unjust and discriminatory use of genetic information.

Existing laws

22. Individual States generally regulate insurance in the United States except for what is covered under the Employee Retirement Income Security Act. Today, many States prohibit insurance companies from using genetic information for the following purposes: (a) to deny applications for a health insurance policy or plan (including determining eligibility), (b) as a basis for imposing pre-existing condition exclusions or (c) to determine benefits or exclusions under a policy or plan. In addition, many States regulate the use of genetic information for rating purposes, either upon initial application/enrolment or renewal.

23. As noted above, the Congress of the United States addressed several key discrimination issues in 1996, in Title I of HIPAA. HIPAA prohibits discrimination in enrolment in group health plans based on health status (including discrimination based on genetic information as a sole determining factor), prohibits increasing the contribution rates of an individual in a group plan based solely on his or her genetic information, and prohibits using genetic information as the sole basis for imposing a pre-existing condition exclusion under a group health plan, in the absence of a diagnosis relating to that information.

Privacy

24. In Title II of HIPAA, the Congress of the United States gave HHS the authority to promulgate a health-information privacy rule that protects certain individually-identifiable health information, including genetic information, possessed by health plans (including health insurance issuers), health-care clearinghouses, and certain health-care providers that transmit health information in connection with particular electronic transactions. The resulting privacy rule is very broad and comprehensive and regulates the uses and disclosures of this information — referred to as protected health information. The rule provides that a covered entity cannot use or disclose protected health information unless the use or disclosure is specifically permitted or required by the rule. Disclosures to the individual are required, as are disclosures to HHS to determine or enforce compliance. The rule permits the covered entity to use or disclose protected health information without the individual's authorization for certain treatment, payment, and health-care operations (including underwriting and other activities related to creation, renewal or replacement of health insurance/benefits). Protected health information can also be used or disclosed without authorization, but subject to specific restrictions, for certain public purposes, such as public health (e.g., to report contagious diseases to public health authorities), law enforcement, research, and other similar purposes. In addition, the rule permits certain other uses and disclosures without the individual's express authorization. However, absent a specific permission in the privacy rule, a covered entity may only use or disclose protected health information for a particular purpose if the individual has provided written authorization. Compliance with the privacy rule was required as of 14 April 2003 for most covered entities, and as of 14 April 2004, for small health plans.

III. Information and comments received from the United Nations system

A. United Nations Educational, Scientific and Cultural Organization

25. Responding to the need for a universal ethical framework, following the adoption in 1997 of the Universal Declaration on the Human Genome and Human Rights and in 2003 of the International Declaration on Human Genetic Data, the General Conference of UNESCO at its 33rd session on 19 October 2005 adopted by acclamation the Universal Declaration on Bioethics and Human Rights. For the first time in the history of bioethics, Member States thus solemnly affirmed the commitment of the international community to respect and implement a certain number of universal principles for humanity in the development and application of science and technology, set forth within a single text.

26. Under the aegis of respect for human dignity, human rights and fundamental freedoms, the Universal Declaration deals with ethical issues raised by medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions, and sets forth universal principles of utmost importance to guide Member States in formulating legislation in this field. Article 11 of the Universal Declaration addresses more particularly the issue of "Non-discrimination and non-stigmatization". Article 9 states that, within the scope of the Declaration, "The privacy of the persons concerned and the confidentiality of their personal information should be respected. To the greatest extent possible, such information should not be used or disclosed for purposes other than those for which it was collected or consented to, consistent with international law, in particular international human rights law."

27. Article 11 of the Declaration does not deal with all forms of legitimate distinctions between people. It focuses only on unlawful, unfair or unjustifiable discrimination between people based on any grounds such as gender, age, ethnicity, disability or other physical, mental or social conditions, diseases or genetic characteristics and the like. The list is not closed. In addition to various forms of discrimination, stigmatization is also prohibited by the Declaration. The history of medical research shows — even in the recent past — a disturbing pattern of discrimination against different groups, including "races", ethnic minorities, and women. During the conceptualization of research and the establishment of control groups, culturally, morally or legally problematic categories may be used, and the avoidance of discriminatory practices requires communication between the relevant disciplines.

28. It is significant that the UNESCO Declaration has already been cited as a relevant international text, for instance in a recent judgment of the European Court of Human Rights.

29. It is very important to note that the text of the new Declaration is the beginning rather than the end of a process of internationalization of bioethics. Therefore, special attention must be given to the application of the principles and the dissemination and the promotion of the Declaration. Member States that have not already done so will be encouraged to establish bioethics committees; to promote informed pluralistic public debate; to foster bioethics education and training and to take appropriate legal measures to facilitate transnational research.

International organizations such as UNESCO will continue to assist countries in developing an ethical infrastructure so that human beings everywhere can benefit from the advances of science and technology within a framework of respect for human rights and fundamental freedoms.

B. Division for Social Policy and Development, Department of Economic and Social Affairs

30. The Division for Social Policy and Development of the Department of Economic and Social Affairs wishes to draw the following elements to the attention of the Economic and Social Council in its consideration of the follow-up and implementation of its resolution 2004/9.

31. Firstly, the Permanent Forum on Indigenous Issues has been aware and sensitive to issues regarding genetic privacy and discrimination. During its fifth session, in May 2006, the Forum received concrete information and concerns about the Genographic Project, a well-funded multi-million dollar project, and adopted the following specific recommendation in paragraph 88 of its report (E/2006/43) under the item "human rights": "The Permanent Forum recommends that WHO and the Human Rights Council conduct an investigation of the objectives of the Genographic Project which proposes to collect 100,000 DNA samples from the indigenous peoples of the world in order to formulate theories on historic human migrations, that the Genographic Project should be immediately suspended and that they report to indigenous peoples on the free, prior and informed consent of indigenous peoples in all communities where activities are conducted and planned". Following this recommendation, it was reported that the Genographic Project has been suspended.

32. Secondly, during the negotiations of the text of the Convention on the Rights of Persons with Disabilities, a few Member States proposed the inclusion of a reference to genetic privacy. This proposal, along with another suggestion to include in a preambular paragraph a reference to the International Declaration on Human Genetic Data adopted by the General Conference of UNESCO, were not accepted.

IV. Conclusion and recommendation

33. **The issue of genetic privacy and non-discrimination has been on the agenda of the Council on a triennial basis since 2001. During that time, important work has been carried out in this field by United Nations entities, particularly UNESCO. Few responses have been provided to the note verbale sent by the Secretariat for comments on Economic and Social Council resolution 2004/9. Given the limited response and taking into account the fact that the matter is considered in other United Nations forums, the Council may wish to decide on the most appropriate forums at which to consider the issue further.**